DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2015-N-1514]

RIN 0910-AH24

Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products; Request for Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the advance notice of proposed rulemaking (ANPRM) entitled "Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products" that appeared in the Federal Register of July 1, 2015. In the ANPRM, FDA requested comments, data, research results, or other information, that may inform regulatory actions that FDA might take with respect to nicotine exposure warnings and child-resistant packaging for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and

drinks. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the ANPRM published July 1, 2015 (80 FR 37555). Submit either electronic or written comments by September 30, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2015-N-1514 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Requests for Comments and Information" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bryant M. Godfrey or Courtney S. Smith, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1-877-CTP-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 1, 2015 (80 FR 37555), FDA published an ANPRM with a 60-day comment period to request comments, data, research results, or other information, that may inform regulatory actions that FDA might take with respect to nicotine exposure warnings and child-resistant packaging for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks.

The Agency has received several comments requesting an extension of the comment period for the ANPRM. These comments convey concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful responses to questions raised in the ANPRM.

FDA has considered the requests and is extending the comment period for the ANPRM for 30 days, until September 30, 2015. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential regulatory action on these important issues.

II. Requests for Comments and Information

A. General Information About Submitting Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

B. Public Availability of Comments

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov. As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on http://www.regulations.gov. This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category "Individual Consumer" under the field entitled "Category (Required)", on the "Your Information" page on http://www.regulations.gov; for this ANPRM, however, FDA will not be following this general practice. Instead, FDA will post on http://www.regulations.gov comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on http://www.regulations.gov if you include that information in the body of your comments. For electronic comments submitted to http://www.regulations.gov, FDA will post the body of your comment on http://www.regulations.gov along with your State/province and country (if provided), the name of your representative (if any), and the category identifying you (e.g., individual, consumer, academic, industry). For written submissions submitted to the

Division of Dockets Management, FDA will post the body of your comments on http://www.regulations.gov, but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

Dated: August 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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